Exhibit 33

ASCO™

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

REFORM OF THE MEDICARE PAYMENT METHODS FOR CANCER CHEMOTHERAPY

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TABLE OF CONTENTS

REFORM OF THE MEDICARE PAYMENT METHODS FOR CANCER CHEMOTHERAPY

Legislation enacted in 2000 contemplates that, following a study by the General Accounting Office, Medicare payments for drugs and drug administration services will be restructured to reduce the payment amounts for drugs while increasing the payment amounts for related services. This paper summarizes the issues involved and sets forth the positions of the American Society of Clinical Oncology (ASCO) on the restructuring. ASCO is the national organization representing physicians and other health care professionals who specialize in the treatment of cancer. ASCO has approximately 16,000 members, primarily physicians, who work in academic medical centers, community-based office practices, and other settings throughout the United States (and in other countries as well). ASCO consulted a number of other organizations in preparing this paper, but the paper represents only the position of ASCO except to the extent that other organizations separately endorse it.[1]

In brief, ASCO's position is as follows:

Restructuring of payments -- ASCO supports restructuring Medicare payments for drugs and related services to reduce the payment amounts for drugs and to appropriately increase the payment amounts for the related services.

No adverse effect on health care -- In restructuring payment methods, it is imperative that the Medicare program maintain the quality and safety of care for cancer patients, that it not restrict, deny, or reduce access to care, and that it guard against unintentional consequences of these payment changes. There must not be any adverse impact on patient participation in clinical research, provision of care in rural and underserved areas, the continued

[1] ASCO consulted the American Society of Hematology, American Society of Pediatric Hematology/Oncology, Administrators in Oncology/Hematology Assembly, National Coalition for Cancer Survivorship, Oncology Nursing Society, and Society of Gynecologic Oncologists.

role of specialized oncology nurses, and the maintenance of other important components of cancer care.

Payments for drug administration -- The Medicare payments for drug administration should cover the full costs incurred by physicians in providing such services. Since the current "top down" methodology is seriously flawed in setting payment rates for services that lack a physician work component, and there is no apparent means within the top down methodology to resolve these problems, ASCO recommends use of the "bottom up" methodology to establish payment amounts for drug administration and other significant services that lack a physician work component.

Cognitive services -- Medicare should establish a new payment mechanism for chemotherapy support services to recognize payments for important services that are furnished in connection with chemotherapy but that are not now reimbursed.

Payments for drugs -- Medicare payment for drugs should be based either on (1) government surveys of wholesaler selling prices, or (2) the existing average wholesale price system as modified to limit the permissible difference between actual selling price and published average wholesale price. Any payment system based on an estimate of market prices should include an add-on percentage to cover certain additional costs.

I. INTRODUCTION

A. Use of Drug Therapy in the Treatment of Cancer

Medicare covers injectable drugs administered incident to a physician's service and a small number of oral drugs. Although the proposed restructuring of Medicare payments would affect all Medicare-covered drugs, it would particularly affect cancer therapy because drugs are central to the treatment of cancer and because about half of all cancer patients are covered by Medicare.

Chemotherapy is one of the primary methods for treatment of cancer, in addition to surgery and radiation therapy. Most cancer chemotherapy is furnished to patients by medical oncologists, although some surgeons furnish post-surgery chemotherapy. Urologists also

provide drug therapy, typically hormonal therapy, to their prostate cancer patients. Medical oncologists, however, concentrate on chemotherapy, and appropriate payments for that service are therefore key to whether they are able to carry on their practices.

Cancer chemotherapy has undergone important changes in recent decades. In the 1970s, there were few drug treatments available, and those that were available were generally administered to hospital inpatients. The 1980s saw important advances in chemotherapy as well as movement of the procedure from the hospital inpatient setting to outpatient departments and physician offices. Chemotherapy began moving to the office setting in the early to mid-1980s when doxorubicin was determined to be effective for many tumor types, and, together with 5-FU, cyclophosphamide, and methotrexate, those drugs were the principal anticancer agents used in the office.

In the late 1980s and 1990s, a number of new chemotherapy agents were introduced, and the development of effective antinausea drugs made it possible to transfer additional types of treatment from the hospital inpatient setting to the hospital outpatient department and the office. Outpatient chemotherapy became much more complex during this period compared to the relatively simple procedures of the early 1980s. Outpatient chemotherapy began to include the use of multiple antineoplastic agents, pretreatment medications, antinausea agents, extended hydration, and other complexities. Currently, almost all adult cancer patients receive chemotherapy as outpatients, and the large majority of those are treated in physician offices.

Administration of chemotherapy is a complex and time-consuming process that does not at all resemble what most people envision when they think of drug administration in physician offices and outpatient departments. Chemotherapy drugs are toxic agents that usually come in powder form and must generally be mixed with an appropriate solution in a biological safety cabinet. Administration of the drugs is often preceded or followed by the separate administration of antiemetics, steroids, and other drugs and by prolonged infusion of saline solution for hydration purposes. The staff administering the drugs are typically oncology

certified nurses, who are specially trained registered nurses. The drugs are usually administered by "push" or by infusion into a vein or a previously implanted venous access device. In a push, the nurse slowly administers the drug from a syringe over a relatively short period of time, while an infusion can take from 20 minutes to several hours as the drug is transferred from a bag. Chemotherapy is also sometimes administered by "continuous infusion," a process in which an external infusion pump, filled and initiated in the office, is used to administer a chemotherapy agent over a period of several days. Various adverse events can occur during the chemotherapy administration, including extravasation of the drug into tissue, nausea and vomiting, fluid volume overload leading to shortness of breath, fever, and life-threatening events such as anaphylaxis.

Each chemotherapy session is preceded and followed by considerable discussion between the nurse and the patient. The nurse carefully and repeatedly queries the patient about other medications being used, including "alternative" drugs, nonprescription drugs, and drugs prescribed by other physicians, to account for possible interactions. The nurse explains the side effects that may occur during and after the chemotherapy administration, which may include, in addition to those described above, mouth sores, diarrhea, skin changes, and other symptoms.

Since cancer chemotherapy frequently results in significant side-effects after the time of treatment, oncologists spend considerable time managing the effects of the treatment as well as the effects of the disease itself. Because of the very serious nature of cancer, oncologists also typically provide a variety of support services to patients receiving chemotherapy, such as psychosocial services, nutrition counseling, family counseling, and other mechanisms to assist patients in coping with their disease.

In addition to the costs of the specialized staff who administer the chemotherapy, and the cost of the supplies used, the drugs themselves are costly. Physicians furnishing chemotherapy in their offices purchase the drugs, usually from wholesalers and sometimes directly from the manufacturers, and maintain a stock of drugs for use with their patients as needed. Thus, they are at financial risk to recover the drug costs.

Cancer drugs can be very expensive, as two examples will illustrate. First, consider a woman with metastatic breast cancer whose tumor contains the HER-2 protein. The standard treatment would be six courses of a combination therapy of Taxol (paclitaxel) and Herceptin (trastuzumab). The Medicare allowed amounts for the drugs involved would be approximately $24,000.[2] As an another example, a standard treatment for advanced non-small cell lung cancer is Gemzar (gemcitabine) and Platinol (cisplatin). The Medicare allowed amounts for the drugs administered to a typical man over four cycles of treatment would be about $15,000.[3] The size of the payment amounts illustrates that there are large costs involved in maintaining an inventory of anticancer drugs and that even small underpayments to physicians can result in large unreimbursed out-of-pocket costs.

B. History of the Controversy

1. Payments for Drugs

(a) Average Wholesale Price

Apparently from the beginning of the program, Medicare has based payment for drugs on published "average wholesale price" (AWP). AWP is used throughout public and private insurance programs as the basis for drug reimbursement, both for drugs administered in physician offices and for drugs dispensed by pharmacies. The amount of reimbursement varies from plan to plan and setting to setting, but it is almost always expressed as a percentage of AWP.

There are two sources for AWPs -- *Drug Topics Red Book* published by Medical Economics Company, Inc. and data files available from First DataBank, Inc. (A third publisher,

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[2] The woman is assumed to be 5' 7" tall and to weigh 140 pounds (body surface area 1.734 square meters). The Taxol and related drugs, such as the anti-emetics, would have a Medicare allowed amount (95% of AWP) of about $1800 for each of the six cycles. The Herceptin and related saline would have a per cycle cost of about $1805.

[3] The man is assumed to 6', 0" tall and 180 pounds (body surface area of 2.042 square meters).

MediSpan, was acquired by First DataBank in 1998.) AWPs are published for each drug by National Drug Code (NDC) number. An 11-digit NDC number identifies the manufacturer or distributor of the drug, the particular drug, its strength, and its package size.

AWPs are set by the publishers based on information submitted by each drug's manufacturer (or distributor). Apparently the publishers will accept from the drug's manufacturer either the manufacturer's price of the drug to wholesalers (often called the "wholesale acquisition cost" or "WAC") or the manufacturer's statement of the drug's AWP. If the manufacturer submits a proposed AWP, the publishers use that number. If the manufacturer submits its WAC, the publisher adds 20 to 25 percent to that amount to set the AWP. The exact percentage that is added varies depending on the identity of the manufacturer or, in some cases, the line of drugs. The reason why the publishers add 20 percent for some manufacturers and 25 percent for others is not clear but apparently has historical roots. Because the publishers may differ on the amount of the percentage add-on for a particular manufacturer or line of drugs, the published AWPs are not always the same in the two publications.

Although WAC represents the price at which manufacturers typically sell to wholesalers, neither WAC nor AWP is necessarily a reliable guide to the price paid by the end user. That is because manufacturers may have contracts directly with physician groups and other end-users specifying a purchase price. Under these arrangements, a wholesaler is advised of the negotiated price, and the wholesaler sells to the purchaser at that price. The wholesaler then "charges back" to the manufacturer the difference between WAC and the actual sales price, in addition to a service charge. These charge-back arrangements allow drugs to be distributed through normal wholesaler channels while at the same time permitting manufacturers to negotiate prices with specific end-users.

(b) Medicare Payments

Federal authorities have recognized since the 1970s that AWP overstates the price at which drugs can actually be purchased from drug wholesalers, and the appropriate payment

method for drugs has been a frequent issue since then. There is a long history of federal actions to address the AWP issue.

Initially, the Health Care Financing Administration ("HCFA") and the Office of Inspector General ("OIG") focused on payments to pharmacies under the Medicaid program. For example, a 1984 survey of prices actually paid by pharmacies in six states found that prices paid averaged 16 percent below AWP.[4] HCFA required states, in estimating the drug stores' acquisition cost of drugs, to assume a discount from AWP.

In the early 1990s, the government's attention moved from Medicaid to Medicare. As part of its proposal to implement the physician fee schedule, HCFA proposed to reduce the payment for drugs to 85 percent of AWP based on the OIG report indicating that pharmacies were getting an average discount of about 16 percent and an assumption that physicians probably paid no more than pharmacists.[5] Public comments strongly opposed this reduction, and the final rules adopted a uniform national payment based on 100 percent of AWP. The regulations also authorized surveys to determine estimated acquisition costs that could be used -- together with a potential additional factor to cover inventory, wastage, and other costs -- as a substitute for AWP.

In 1994, HCFA began a process to determine estimated acquisition cost by survey for use instead of AWP. HCFA proposed to survey only a handful of physicians in each state and to base the Medicare payment rate on the median acquisition cost of the surveyed group. ASCO opposed this proposal because the sample size was too small and was not scientifically selected. In addition, the proposal to use the median cost as the payment rate could have resulted in large underpayments to some physicians. When HCFA determined that a scientifically sound survey would be too burdensome to carry out, it abandoned the plan.

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[4] HHS OIG Report, "Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs," No. 84-12 (Sept. 1984).

[5] 56 Fed. Reg. 25792, 25800-01 (June 5, 1991).

The Clinton Administration subsequently proposed legislation that would have changed the Medicare payment system from one based on published AWP to one based on what it called actual acquisition cost. The payment amount for a particular drug administered by a specific physician would have been based on the lowest price that the physician had paid for that type of a drug in the preceding six-month period. In addition, payments would have been capped at an amount based on the median national acquisition cost in a prior period. ASCO opposed the proposal because, among other reasons, it would not have paid true acquisition cost and would have imposed burdensome accounting requirements on physicians. Congress did not adopt the Administration's proposal. In 1997, however, Congress lowered Medicare payments for drugs to 95 percent of AWP.

Following that action, the Clinton Administration changed positions and no longer advocated a payment system based on each physician's acquisition cost. Instead, it proposed lowering the Medicare payment rate to 83 percent of AWP. Congress did not adopt that proposal either.

In 2000, HCFA initiated an attempt to substitute catalog prices collected many months earlier by the Department of Justice in place of AWPs for about 50 drugs. Opposition to this initiative led to a reexamination by HCFA of the extent to which the current payment amounts for drugs are necessary to offset underpayments for drug administration services. HCFA concluded that Medicare did underpay for administration services and canceled its plan to use the catalog prices in place of published AWPs. Congress subsequently codified that action by enacting a moratorium on any reductions of drug payment amounts until HCFA has received and considered a General Accounting Office study on the subject.

In summary, there has long been recognition that AWP is greater than the acquisition cost of drugs, but all of the previous attempts to develop an alternative system have

been abandoned or rejected. The only actions actually implemented have been adjustments to the percentage of AWP that is reimbursed by Medicare.[6]

2. Payments for Drug Administration

The issue of the adequacy of Medicare payment for chemotherapy administration services also has a long history. A few years after chemotherapy began to move into the office setting, section 4055(d) of the Omnibus Budget Reconciliation Act of 1987[7] was enacted to require the Secretary of Health and Human Services to study and report to Congress by April 1, 1989, on possible modifications to the Medicare payment amounts to more appropriately reflect the costs associated with providing chemotherapy to patients in physician offices. HCFA subsequently published a notice in the Federal Register requesting relevant data.[8] The notice recognized that Medicare payment for chemotherapy administration may be inadequate:

> "Changes in treatment methods and advances in technology now allow chemotherapy to be furnished to many patients in the physician's office, thus reducing the need for hospitalization to administer chemotherapy. Furnishing these services in the physician's office is more convenient for some patients and may provide other benefits as well.
>
> "Current Medicare Part B payment rules for physicians' services, however, may fail to compensate adequately for these services because the usual reasonable charge methodology may not fully recognize the overhead costs involved in these procedures. Some sources of additional costs include employment of nurse oncologists, special patient rooms, and safety equipment required

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[6] It is noteworthy that private insurers have generally not discontinued use of AWP-based reimbursement systems for drug stores and physicians even though insurers have strong incentives to reduce excessive reimbursement. The reimbursement for medications dispensed by drug stores would be an inviting target if insurers viewed the payment amounts as too high. The fact that insurers continue to use AWP presumably indicates, however, the insurers' judgment that, even though the AWP-based payments exceed the drug stores' expenses for drugs, the aggregate payments they make to drug stores for drugs and dispensing fees are not excessive.

[7] The provision was redesignated as section 4056(d) by section 411(f)(14) of the Medicare Catastrophic Coverage Act of 1987 (Pub. L. No. 100-360).

[8] 53 Fed. Reg. 39644 (Oct. 11, 1988).

> because of the toxicity of the chemotherapeutic agents and safety procedures issued by the Occupational Safety and Health Administration."

Possibly because there was little pre-existing data on the costs of chemotherapy administration, HCFA never conducted the required study and never offered recommendations to Congress.

The adequacy of Medicare payments for drug administration services has been repeatedly tied to the issue of drug payments by those opposing reductions in payments for drugs. In 1991, when HCFA proposed to reduce drug payments to 85 percent of AWP, many of the comments opposing the reduction cited the "shortfalls in chemotherapy administration payments" and warned that "[w]ithout adequate compensation . . . many physicians would perform the service in hospital outpatient departments at substantially higher costs."[9]

It was not until 2000 that HCFA acknowledged for the first time that Medicare payments for chemotherapy administration are too low. HCFA also concluded that its efforts to reduce drug payments should be suspended until the administration payments were increased. In a letter to Congress, HCFA stated:

> "[W]e have concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate. . . . In next year's physician fee schedule regulations, we intend to propose modifications to the practice expense formula or legislation that would increase payments for cancer chemotherapy administration. Our goal would be to have more accurate pricing for both chemotherapy drugs and chemotherapy administration in place at the same time."[10]

HCFA later acknowledged the range of uncompensated services furnished by oncologists that are being funded by the drug payments:

> "[S]ome practitioners have come to rely on inflated drug payments to subsidize associated, non-reimbursed costs, such as storage and

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[9] 56 Fed. Reg. 59524 (Nov. 25, 1991).

[10] Letter from Nancy-Ann Min DeParle, HCFA Administrator, to Members of Congress, dated Sep. 8, 2000.

> administration, and, in some cases, to provide other important services that are not adequately compensated. Consequently, the administrative actions we take to reduce the price of a drug need to take such expenses into account."[11]

3. Payment for Cognitive Services

As is discussed in more detail below, Medicare does not pay for certain services that oncologists routinely furnish to their patients. Some of these, such as psychosocial support services, are furnished by nurses, and there is simply no Medicare payment for them. Other services, such as coordinating care with other physicians, telephone calls with patients, answering e-mail inquiries from patients, and extensive family counseling, are furnished by physicians. Medicare theoretically pays for this work through payments for office visits, but the amount of work involved greatly exceeds any amount that is ostensibly included in the visit payments. The lack of adequate Medicare payment for services related to treatment by chemotherapy is a significant issue for oncologists.

C. Current Status of Issue

Section 213 of the Balanced Budget Refinement Act of 1999 requires the General Accounting Office (GAO) to conduct a "nationwide study to determine the physician and nonphysician clinical resources necessary to provide safe outpatient cancer therapy services and the appropriate payment rates for such services under the medicare program." The GAO is also required to make recommendations on adjustments to the practice expense and physician work components to assure adequate payment for cancer therapy services.

Section 429 of the Benefits Improvement and Protection Act of 2000 expanded the requirements for the study. The GAO is required to study the differences between Medicare

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[11] Memorandum from Michael M. Hash, HCFA Acting Administrator, to June Gibbs Brown, Inspector General, dated Dec. 6, 2000, included as App. F to HHS OIG report "Medicare

payments for drugs and the prices paid for the drugs by physicians and others. In addition, a requirement similar to the provision in the 1999 legislation directs the GAO to determine the extent to which Medicare payments are inadequate to compensate physicians and others for the costs incurred in the administration, handling, and storage of drugs. The GAO is required to consult with physicians and others in conducting the study.

The GAO must submit the study, including specific recommendations for revisions to the Medicare payment methods, to Congress and the Secretary of Health and Human Services by September 2001. The recommendations must be designed to insure that Medicare beneficiaries continue to have appropriate access to health care services. In developing the recommendations, the GAO is required to consider (1) drug payments made by private large group health plans, (2) the potential that any recommended changes in payments would have to transfer treatment from the office back to the hospital setting, and (3) the effect of recommended changes in payment methods on hospital outpatient department reimbursement.

Based on the GAO's recommendations, HCFA is required by the legislation to revise the Medicare payment method for drugs and is authorized to revise the payment amounts for drug administration services and to establish new types of payments to physicians and other providers. These changes can be implemented without further legislation. The only statutory restriction is that the aggregate payments for drugs and for any new types of payments cannot exceed the aggregate amount that would have been paid for drugs under the current system.

Pending HCFA's review of the GAO report, the law imposes a moratorium on any reductions in Medicare payments for drugs. HCFA may not directly or indirectly decrease the Medicare payment amounts that were in effect on January 1, 2001.

Reimbursement of Prescription Drugs" (Jan. 2001).

II. ADVERSE CONSEQUENCES OF INADEQUATE PAYMENT

ASCO supports restructuring Medicare payments for drugs and related services. It is essential, however, that the aggregate resulting payments be sufficient to support the continued delivery of quality care to cancer patients.

If Medicare payments for office-based chemotherapy services were reduced significantly, oncologists would be financially unable to furnish chemotherapy in their offices and would instead refer patients to hospitals for treatment. Putting aside the question of whether Medicare payments to hospitals for chemotherapy are adequate, hospitals simply lack capacity to accommodate the massive inflow of cancer patients that would result if oncologists no longer furnished chemotherapy in their offices. Since the large majority of cancer patients are currently treated in physician offices, many hospitals would probably need to double or triple their outpatient oncology capacity.

Whether hospitals would expand in this way is unknown. Substantial capital investment would be needed, and whether that expenditure would be forthcoming would likely depend on how hospitals viewed the adequacy of Medicare payments as well as the availability of funds. Even if hospitals engaged in a nationwide effort to expand oncology facilities, there would undoubtedly be a period of years during which the country's health care system no longer delivered quality cancer treatment. Patients would face long delays in obtaining chemotherapy in the limited available facilities, therapy could often be scheduled at night, courses of chemotherapy might be limited, and support services would be unavailable to many. Rural and underserved areas would be particularly affected, since hospitals with capacity could be a long distance from patients in such areas, and hospitals in those areas would probably be the slowest

to develop new facilities. It is a nightmarish scenario that must be avoided by preserving the financial viability of office-based chemotherapy.

Returning to the old practice of administering chemotherapy to hospital inpatients is not a viable option. Medicare rules do not permit inpatient treatment of individuals who need only outpatient therapy.

Less drastic reductions in Medicare payments for oncology services might imperil quality cancer care even if physician offices continued to furnish chemotherapy. To live within smaller Medicare payments, oncologists might be compelled to reduce staffing levels and replace highly skilled oncology certified nurses with lower-paid assistants. Less staff time would be available during the chemotherapy sessions to educate patients and monitor for ill effects. Qualified nurses would no longer be readily available to respond to patients' inquiries about their treatment and its side effects. Seriously ill cancer patients would not have the support services that oncologists' offices now provide and would have to struggle on their own in coping with their life-threatening disease.

Patient participation in clinical trials offering state-of-the-art treatment would dwindle if oncologists' offices no longer have the staff to perform the trial-related administrative functions. An ASCO study has shown that participation in clinical trials already results in financial losses for physician offices, and further financial pressure would likely cut participation sharply, resulting in adverse consequences for patient access to the newest therapies.[12]

The United States currently has a superb delivery system for cancer treatment. The decision on how to restructure Medicare payments for chemotherapy will determine whether

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[12] Unpublished data from study presented at ASCO Annual Meeting, May, 2000.

the quality of that system continues. ASCO will strongly oppose any changes in the payment system that would degrade the quality of care furnished to cancer patients.

III. PAYMENTS FOR DRUG ADMINISTRATION

A. Drug Administration Codes

There are two principal sets of drug administration codes that are published in the CPT code book[13] and used by Medicare. One series of codes (96400-96549) is for chemotherapy administration services. These codes are accorded higher payment rates because there is more work involved in administering toxic anticancer drugs than is involved in the administration of other types of drugs. Medicare policy limits use of these codes to patients with a diagnosis of cancer.

Although the use of the chemotherapy administration codes is generally straightforward and consistent with their descriptions in the CPT, Medicare has a special policy for use of 96408 (administration by push technique) that differs from the rules in the CPT. This code may be reported only once per day for a patient regardless of the number of drugs administered by push.

The other main code series is 90780-90788. These codes are used for administration of drugs other than chemotherapy drugs. The codes are also used for administration of saline solution for hydration, which is common in many chemotherapy regimens. Generally, Medicare pays only for the infusion codes 90780-81 and not for the codes

[13] *Current Procedural Terminology*, published by the American Medical Association.

used for intramuscular and other methods of administration. Although Medicare paid for non-infusion injections at one time, when the physician fee schedule was introduced in 1992 the program adopted a policy of making no payment for non-infusion administration unless it is the only other service furnished to the patient on that day.

There are also a few other specialized drug administration codes, such as the code for instillation of a chemotherapy agent into the bladder (51720).

B. Source of the Current Payment Levels

The current Medicare payment amounts for chemotherapy administration services are substantially less than the costs incurred to furnish them. This situation appears principally to be a residual consequence of chemotherapy moving from the hospital to the office setting at a time when increases in Medicare allowed charges were legally constrained.

Prior to introduction of the physician fee schedule in 1992, Medicare payments were based on "reasonable charges," but the permissible annual increase in the Medicare allowed charges was limited since the mid-1970's by the rate of increase in the Medicare Economic Index. This limitation was intended to prevent Medicare payments for physician services from rising faster than the increase in the costs generally being incurred by physicians.

It appears that the early charges for office-based chemotherapy were set at a time when most chemotherapy was furnished in hospitals, and chemotherapy in the office setting was limited to simple types. As the more complicated forms of chemotherapy migrated from the hospital to the office, the Medicare payment rates did not change to account for the increased complexity because the same billing codes were used and increases in payments for those codes could not exceed the increase in general physician costs as reflected in the Medicare Economic Index. Thus, the allowed charges in the 1980s for chemotherapy furnished in physician offices reflected simpler chemotherapy procedures from an earlier era.

When the physician fee schedule was implemented in 1992, this situation was not remedied because the payments for practice expenses were still linked to the previous allowed

charges. Only the physician work components of the relative values were based on estimates of the resources used to provide each service. The practice expense and malpractice components were, as required by statute, based on Medicare allowed charges in 1989, subject to a budget-neutrality adjustment.

In the late 1990s, the practice expense components were made resource-based. The conversion of the practice expense components from being based on 1989 allowed charges to being based on the resources actually used to furnish services presented an opportunity to resolve the inadequacy of chemotherapy administration payments. Although HCFA initially pursued an approach that might have increased payments to cover costs, it ultimately adopted a methodology that preserved the status quo instead.

When HCFA began the process to establish resource-based practice expense components, it first proposed a "bottom up" approach. Under this method, clinical practice expert panels (CPEPs) were formed to estimate the staff time, supplies, and equipment used in each service. It was HCFA's initial plan to estimate the other, "indirect" costs involved based on a survey of physicians' costs. When that survey method proved to be impracticable, HCFA developed an alternative method to estimate those costs.

Because the bottom up methodology would have resulted in significant shifts of Medicare payments among various specialties, Congress enacted legislation postponing implementation of the resource-based practice expense components for one year and specifying new criteria for HCFA to consider in adopting a methodology. As a result, HCFA changed to a "top down" methodology.

The top down methodology started with the practice expenses per hour of physician work as determined for each specialty through surveys from the American Medical Association's Socioeconomic Monitoring System. The direct practice expenses (clinical staff, supplies, and equipment) as so estimated were allocated to individual codes separately from all other costs (the indirect costs). The total number of practice expense relative value units in the system was kept constant.

HCFA's original proposal for implementation of the top down methodology would have resulted in large reductions in the payment amounts for the principal chemotherapy administration codes. Similar and larger reductions were also seen for many other codes that were technical only and had no physician work value. These reductions were apparently the result of the proposed methodology for allocating indirect costs, which was based in large part on the amount of physician work relative value units assigned to each code and which therefore assumed that services lacking a physician work component did not generate many costs. That implicit assumption was clearly wrong.

To address this concern, HCFA adopted a special methodology for codes that lack a physician work value in which a "zero work value pool" was created for all of those codes. Although HCFA has never published an explanation of this methodology, the pool reportedly is assigned dollars based on the practice expenses per hour of the *average* physician, and non-physician time for each procedure is substituted for the physician time that would otherwise be used. The result of the special methodology was generally to maintain Medicare payment amounts at approximately the same levels as existed prior to institution of the resource-based system. Indeed, some observers have hypothesized that HCFA selected this particular zero work value methodology precisely because it tended to maintain the status quo in payment amounts.

In summary, the current Medicare payment amounts for drug administration services have no relationship to actual costs. The payment levels originated under the previous reasonable charge system at a time when there was little office-based chemotherapy, Medicare rules prohibited increases as complexity grew, and the special methodology adopted by HCFA for zero work value codes simply maintained the approximate prior payment amounts.

C. Inadequacy of the Current Payment Levels

Over the past few years, HCFA has supervised an elaborate procedure to develop estimates of the costs to a physician practice of furnishing chemotherapy. The estimates, which have been confirmed by several reviewing bodies, including HCFA itself, demonstrate that the current Medicare payment amounts are grossly inadequate.

As part of the initial bottom up methodology, a clinical practice expert panel (CPEP) estimated the direct costs of the principal chemotherapy administration codes. These estimates were then reviewed and approved by the Validation Panel that was also part of the bottom up process. Subsequently, the estimates were reviewed and revised somewhat by the American Medical Association's Practice Expense Advisory Committee and its Relative Value Update Committee as a part of the top down refinement process. Finally, HCFA published the estimates in the Federal Register for comment, and, although HCFA initially proposed to reduce the estimate somewhat, HCFA ultimately approved the estimate that the AMA recommended.[14]

The principal component of the direct costs is nursing time, which is estimated at 121 minutes for CPT 96410 (first hour of an infusion). This time is composed of 55 minutes of pre-procedure time, 27 minutes for the infusion itself, and 39 minutes of post-procedure time. In making the estimates, aspects such as patient education and follow-up telephone calls were averaged over the procedures that would occur during a course of therapy. The 27 minutes of intra-service infusion time represents time actually devoted to the patient by the nurse during the infusion and does not include time during the first hour of infusion when the nurse may periodically perform other tasks. The nursing time estimate for CPT 96408 (administration by push) is the same for pre- and post-procedure time and differs from 96410 in that only 15 minutes is estimated for the administration itself, for a total of 109 minutes. Details of the estimates for clinical staff, supplies, and equipment used for 96408 and 96410 are attached as Appendix A.[15]

Although the CPEP process estimated direct expenses, the bulk of practice expenses are the indirect expenses such as administrative staff, rent, and other overhead costs.

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[14] 65 Fed. Reg. 65376, 65392-93 (Nov. 1, 2000).

[15] The supply costs were estimated prior to enactment of the Needlestick Safety and Protection Act. The new requirements in that act for safer medical devices may increase these costs, and Medicare payments should reflect those higher costs.

Using the general ratio between direct and indirect expenses for all physicians,[16] the net total cost of the two principal chemotherapy administration codes is shown in the following table compared to the Medicare payment amount:

CPT 96408 (administration by push)	
Clinical staff	$ 50.69
Supplies	9.89
Equipment	0.40
Total direct costs	60.98
Indirect costs	122.78
Total costs	**$ 183.76**
Medicare payment	**$ 39.02 (21% of cost)**

CPT 96410 (first hour of infusion)	
Clinical staff	$ 60.14
Supplies	26.68
Equipment	1.84
Total direct costs	88.66
Indirect costs	178.51
Total costs	**$ 267.17**
Medicare payment	**$ 62.36 (23% of cost)**

As these totals indicate, Medicare pays less than one-fourth of the costs of the basic chemotherapy administration services. Although similar estimates have not been developed for the other chemotherapy administration codes and for the non-chemotherapy drug administration codes, it is likely that there would be similar large discrepancies.

D. Revision of the Payments for Drug Administration

[16] According to HCFA, the AMA survey indicates total practice expenses of $67.50 per hour of physician work, of which $22.40 is direct expenses (clinical staff, supplies, and equipment) and $45.10 is indirect expenses (clerical staff, office expense, and other expense). 63 Fed. Reg. 30818, 30830 (June 5, 1998). Thus, indirect expenses are 66.8% of total expenses.

As HCFA has recognized, and as the CPEP data demonstrate, the Medicare payments for chemotherapy administration are seriously inadequate. The payment amounts for infusions of other types of drugs (CPT codes 90780-81), such as antiemetics, also appear to be significantly less than the costs involved. ASCO's position is that Medicare should pay the full costs reflected in the CPEP data for the principal chemotherapy administration codes and should make comparable payments for the other types of drug administration services, as adjusted to reflect differences in the clinical staff time, supplies, and equipment involved.

The current top down methodology used by HCFA does not permit adjustment of the payment amounts for individual codes. Consequently, the question has been raised as to how this result can be achieved within the current methodology. For the reasons set forth in the following section, ASCO believes that the current top down methodology is flawed in its treatment of technical services such as drug administration and that an equitable result cannot be reached through use of the top down approach.

1. Problems With the Methodology

(a) Aggregate Underpayment of Practice Expenses

A serious threshold problem is that the top down methodology does not result in full Medicare payment even for those practice expenses that the methodology determines exist. The total number of practice expense relative value units under the top down methodology was set at the same number as had existed under the predecessor method, and thus the methodology is not designed to fully pay all practice expenses. Although HCFA has stated that it cannot determine the percentage of practice expenses that are paid in the aggregate, it has been estimated to be only about 70 percent.

This underpayment of practice expense costs is not relevant to the Medicare program as a whole. Since overall payments are fixed by budget neutrality requirements, the underpayment of practice expenses simply results in additional payments for physician work. Because most physicians receive additional compensation for their personal work that offsets the

underpayment of practice expenses, physicians in general are in the same position they would be in if Medicare fully paid practice expenses.

For services that do not have a physician work component, however, underpayment of the practice expense component means that physicians lose money when furnishing the services. If those services constitute a substantial part of a physician's practice, as they do in the case of drug administration services for oncologists, the underpayment makes it impossible to carry on a practice unless there is an offsetting payment elsewhere. The payments for drugs constitute such an offsetting payment under the current system. But since the top down methodology systematically underpays practice expense components, it will never be adequate by itself to compensate oncologists for their drug administration costs. It is simply not acceptable for Medicare to pay less than the actual costs of providing a service, as it does now in paying only about 70 percent of the system-wide aggregate practice expense costs, when there is no physician work component or other payment to cover the shortfall. In such a case, the practice expenses and malpractice expenses must be paid in full.

(b) Treatment of Codes with Zero Work Values

The top down methodology does not adequately deal with the codes that have no physician work component. As noted above, the top down methodology as originally proposed would have led to drastic reductions for many services that lack a physician work component, apparently because the allocation method for indirect costs relies heavily on the size of the physician work component of each code. In an attempt to prevent those reductions, HCFA adopted, as an interim step, a special pool for codes with a zero work value. It is noteworthy, however, that HCFA has been unable to develop a permanent revised system in the several years since the interim measure was adopted, apparently because the issue presents difficult methodological issues that HCFA has not resolved.

While the æro work value pool methodology was useful as an interim measure because it avoided the large reductions that would otherwise have occurred, its methodological soundness is open to serious question. The fact that HCFA has never published an explanation

of the methodology hampers ASCO's efforts to analyze it, but there are at least several reasons why it appears to be defective.

First, we understand that the number of dollars allocated to the pool is based on the practice costs of the average physician. It is wholly inappropriate to determine the payment amounts for some of oncologists' principal services based on the hourly practice expenses of the average physician, which are considerably lower than those of oncologists.

Second, it is unclear whether there is any validity to substituting nurse and technician time for physician time in a methodology that is ostensibly based on practice expenses per hour of physician work as determined by survey.

Third, in allocating the dollars in the pool to each code, all nurse and technician time is apparently treated equally even though oncology certified nurses are the most highly paid of the various staff types in the HCFA system.

Fourth, the methodology does not necessarily recognize oncologists' full indirect costs. Oncologists' indirect costs (administrative staff, rent, utilities, overhead, etc.) may well be a higher percentage of total costs than the indirect costs of other specialties because of the higher administrative staff costs generated by the preauthorization requirements and disputes with third-party payers over drug coverage that are common in oncology practices.

Finally, the size of the pool and its allocation among the various included codes depends heavily on the minutes of estimated nurse time involved, and there is no assurance that these times have been estimated correctly for the non-oncology services in the mix. Thus, even if the size of the pool were correctly calculated, it may be misallocated to non-oncology codes because the nurse or technician time for those other codes is overstated.

(c) Inadequate Data on Oncologists' Practice Expenses

Although a principal flaw of the interim zero work value pool methodology is its use of the costs of the average physician rather than oncology-specific costs, the use of the HCFA practice expense data specific to oncologists would not solve this problem, since the data on oncologists' practice expenses used by HCFA are unreliable.

(i) *Unrepresentative Sample* -- The sample size of oncologists who were questioned in the AMA survey about their practice expenses is very small. The survey data originally used by HCFA included only 27 oncologists, and the later addition of a fourth year of data increased the sample to only 34 respondents. Among ASCO's membership alone, there are some 4,500 physicians who are board-certified in medical oncology or hematology-oncology. The inadequate sample size by itself makes the data suspect.

The representativeness of the sample is specifically drawn into question by looking at the reported costs. The extraordinary variation in the costs reported by oncologists in the survey is reflected in the summary chart attached as Appendix B. The low practice expenses of many of the oncologists who participated in the survey indicate plainly that they do not furnish chemotherapy services in their offices. This sample is thus inconsistent with the reality that the large majority of chemotherapy services are furnished in physician offices.

Moreover, an important premise of the top down methodology is that physicians who identify themselves as "oncologists" in the AMA survey process are a representative sample of physicians who classify their specialty as "medical oncology" or "hematology-oncology" in the Medicare program. If there were large numbers of physicians in the sample size, minor discrepancies between these groups probably would not matter. But in the case of oncologists, for which the sample size is very small, a few physicians who call themselves "oncologists" to the AMA but, for example, call themselves "surgical oncologists" to HCFA could greatly distort the results as applied to medical oncologists. Some of the "oncologists" in the AMA survey data reported spending time in surgery, which suggests that they may indeed have been surgical oncologists. In addition, an astonishing 42 percent of the oncologists in the three-year sample indicated that they are solo practitioners even though solo practitioner medical oncologists are relatively rare. These 42 percent, whose practice costs obviously were major factors in the result, were probably surgical oncologists or some other type of oncologist who furnishes little or no office-based chemotherapy.

Another indication that the sample is flawed is the inclusion of physicians in multispecialty practices. Some 12 percent of survey respondents were in multispecialty practices and therefore probably reported the average practice expenses for their entire practices, rather than the higher oncology-specific costs.

(ii) *Adjustment for Drug Costs* -- Not only are the survey data on oncologists' practice expenses inherently suspect, they cannot be used without estimating the expenses for drugs that are included in those costs, and HCFA does not have an appropriate method for doing that. The AMA survey data included both drugs and other supplies in a single category, and HCFA's methodology requires an estimate for non-drug supplies only. The survey data for oncologists indicated a supply cost of $ 87.20 per hour of physician work, and to remove drug costs from that total, HCFA arbitrarily reduced the amount to the "all physicians" rate of $ 7.20 per hour.[17]

This adjustment was inappropriate. In the first place, it is most unlikely that oncologists have supply costs that are no higher than the average physician. As the CPEP data indicate, there are significant supply costs associated with every chemotherapy procedure. In addition, while the nurses are furnishing chemotherapy procedures and using the associated supplies, the oncologists are seeing patients and incurring the same kinds of supply costs that other physicians who see patients incur.

Moreover, no adjustment was made to the supply costs of other specialties, even though their supply costs undoubtedly included drug costs and, in some cases, significant drug costs. Oncology was singled out for the adjustment. This had the effect of assigning excess practice expense relative value units to the other specialties, to the detriment of oncology.

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[17] 63 Fed. Reg. 30318, 30830, 30832 (June 5, 1998); 63 Fed. Reg. 58814, 58825 (Nov. 2, 1998).

2. ASCO's Proposal on Drug Administration Payments

(a) Payment of Full Costs

Since, for the reasons just outlined, it does not appear to be possible to work within the top down methodology to achieve appropriate payment amounts for drug administration services, ASCO recommends that the payment amounts simply be revised to cover the full costs of the services. The same approach could be taken to set payment amounts for other zero work value codes, at least those codes that represent significant proportions of the practice expenses of the specialties involved. In effect, HCFA would use the bottom up methodology for codes that do not have a physician work value while continuing to use the top down methodology for the other codes. Since neither HCFA nor any other party that we are aware of has identified an appropriate method for dealing with the zero work value codes within the top down methodology, ASCO believes that this approach is the best available method.

(b) Payment for Multiple Pushes and Infusions

When the chemotherapy administration codes were revised about 1990, the multiple push codes that had existed were condensed into a single code (96408). Because the practice expense components for the 1992 fee schedule (which used the new single push code) were based on 1989 charge data (which used the old multiple codes), HCFA averaged the 1989 charges for the various push codes to establish the component sizes for the new 96408 code. As a result, the current code is interpreted as covering one or more pushes, since charges for multiple pushes went into the calculation.

Now that the practice expense components are resource-based, the payment for 96408 should accurately reflect the costs of multiple pushes. The CPEP data on the costs of 96408, however, were estimated based on the costs of pushing a single drug. If more than one drug is administered in an encounter, there would be additional clinical staff time to prepare the additional drugs, educate the patient about their side effects, and administer them, and there would be additional supply costs. Whatever payment methodology is adopted should insure that there is adequate payment for multiple pushes.

A similar issue is presented in the case of multiple infusions. Medicare policy permits billing only one infusion per day per patient, even if multiple drugs are administered. The billing is adjusted to reflect the total length of the infusion with the multiple drugs, but the time of the infusion by itself does not completely account for the costs involved. When more than one drug is infused, there is additional preparation time and additional supply costs. The Medicare payment for multiple infusions should cover all the additional costs.

IV. PAYMENT FOR CHEMOTHERAPY-RELATED COGNITIVE SERVICES

A. Background

Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement from Medicare and other insurers. These uncompensated services fall into two categories. The first category is composed of services furnished by non-physician staff that are indirectly related to chemotherapy administration and are an integral part of cancer treatment as it is furnished today. These services include nutrition counseling, social worker services, and psychosocial support.

Social worker services encompass a variety of services intended to help patients carry out their therapy. These are functions such as helping patients with their health insurance, filling and refilling prescriptions, and obtaining prosthetics (e.g., breast prostheses and wigs); arranging physical therapy and transportation to and from the office for treatment; and implementing hospice referrals. Psychosocial support includes services such as counseling patients on their activities of daily living, support groups that meet in the physician's office, and grief counseling. These services are not offered by physicians who treat most types of illnesses, but they have become an integral part of cancer treatment.

The second category of services is physician services. Oncologists must frequently perform greater work before and after patient visits than is accounted for in the Medicare relative values for office visits, which assume that such pre- and post-visit work is the same for all specialties. Responding to patient e-mails and extended telephone calls with patients and their families about the side effects of treatment and the progress of the patients'

condition are commonplace, as is in-person family counseling, but Medicare does not make any separate payment for these activities. Oncologists frequently consult by telephone with other physicians on treatment options and the availability of clinical trials. Treating cancer is a multidisciplinary exercise, and medical oncologists must often coordinate with radiation and surgical oncologists. Due to the severity of the disease, physicians treating cancer patients must also complete an extraordinary number of forms to document disability for insurance companies, support applications for family leave, obtain help with utility bills or handicapped license permits, deal with the Immigration and Naturalization Service or the Red Cross so foreign or military family members can visit the patient, and so forth. Medicare's implicit position that oncologists treating patients with cancer have the same amount of pre- and post-visit work as physicians treating relatively healthy patients does not reflect reality and results in a failure to compensate all of the work furnished by oncologists to Medicare patients.

At present, the Medicare and other insurance payments for drugs administered to patients help support these services. But if the restructured payment amounts are closely aligned with the costs of the drugs and the drug administration services, there will be little or no financial support for the related services for which there is no explicit Medicare reimbursement. The underfunding would be particularly problematic in the case of patients taking oral cancer drugs, for which there would not even be the increased payments for drug administration services.

B. ASCO Position

Medicare should establish a new payment for services to patients who are receiving any form of cancer chemotherapy. This payment would compensate physicians for their services, and the services of their staff, that are related to the drug therapy and its side effects but for which there is no specific Medicare reimbursement. ASCO suggests that the payment be designated as covering chemotherapy support services and that it be paid for each week that a patient is undergoing active chemotherapy treatment, whether the drugs are administered in the office or are oral antineoplastics.

The legislation authorizing HCFA to revise Medicare payments related to chemotherapy permits HCFA to establish "new payments" to cover chemotherapy-related costs. This authority would be the legal basis for the additional payment. HCFA, in consultation with ASCO, would estimate the practice costs and physician work time involved, and would set payment amounts that would fully compensate for those costs and that time.

V. PAYMENT FOR DRUGS

A. Current Payment Method

As was discussed in detail above, Medicare currently pays for covered drugs based on 95 percent of average wholesale price ("AWP"). The use of AWP has been criticized, however, because of the large disparity between AWP and actual selling price for some drugs.

The difference, or the "spread," between AWP and actual selling price varies greatly depending on the drug involved. For cancer drugs, the spread is usually narrow in the case of single source drugs that do not have easily substitutable competitors. That is because the manufacturer's list price for such drugs, upon which AWP is based, is typically the price at which sales to wholesalers actually take place. Thus, after the wholesalers mark up the manufacturer's price, there is a relatively small remaining difference between the AWP and actual selling price. For example an OIG study of purchases by New York physicians found spreads of 12 to 18 percent between prices of drugs purchased from wholesalers and AWPs for the single source drugs involved.[18]

The spreads between AWPs and actual sales prices can be quite different in the case of multiple source drugs and single source drugs for which there are competitive products (e.g., antiemetics). In such cases, the manufacturers' list prices, upon which the AWPs are based, tend to remain high and stable, while marketplace competition results in transactions at prices that are sometimes significantly lower. Contracts between manufacturers and end-users involving charge-back arrangements are responsible for much of the difference between actual

[18] "Physicians' Costs for Chemotherapy Drugs," HHS OIG (Nov. 1992).

selling prices and published AWPs. The OIG study of purchases by New York physicians showed spreads for multiple source drugs ranging from 9 percent to 82 percent.[19]

B. Possible Revisions in Medicare Drug Payment Methodologies

There have been a number of proposals to revise the Medicare payment method for drugs to make the payment amount more closely match the cost of the drug to the physician. There are significant practical problems in such a revision because drug prices change frequently and all physicians do not pay the same price.

Provided that Medicare payment methods are revised to pay the full costs of drug administration services and the related cognitive services as discussed above, ASCO supports a revised methodology that lowers the payment amounts for drugs if certain criteria are satisfied: (1) the Medicare payment must fully cover the prices paid by the vast majority of physicians throughout the country who purchase the drug; (2) the payment must also cover the costs related to purchase and use of the drug that are not covered by the payment for administration services; and (3) the methodology must not increase the administrative burden on physicians.

Two types of revised methodologies appear to satisfy these criteria. One possible approach would be a method based on government surveys of wholesalers' market prices, in which the price as so determined would be increased by a factor to account for additional costs, and that amount would be the basis for the Medicare payment. A second possible approach would be an AWP-based methodology in which the AWPs are made more accurate. These possible methodologies, as well as other approaches are discussed in the following sections.

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[19] The large spreads often seen for multiple source drugs do not have the same effect in the Medicaid program as they do in the Medicare program even though both programs base reimbursement on AWP. That is because Medicaid reimbursement is subject to federal upper limits that, in general, cap payments at 150 percent of the lowest published price in the case of multiple source drugs (42 C.F.R. § 447.332). Although the mechanism is imperfect, the federal upper limits tend to substantially reduce payment amounts when the spread between AWP and actual prices is large.

1. Methodologies Based on Market Prices

Those who are dissatisfied with AWP as a basis for Medicare drug payments have often proposed using some method for directly determining the prices at which physicians purchase drugs. ASCO can support that approach if a few conditions are met: (1) the method must use surveys of market prices that are conducted in an accurate and timely fashion; (2) the payment method must use the market prices in a manner such that the Medicare payment will cover the price paid by the vast majority of physicians; and (3) there must be an add-on payment to cover related costs. Those points are discussed in the following sections.

(a) Market Place Survey

A survey of the market to determine the actual prices at which wholesalers sell drugs to physicians, after consideration of discounts, would be relatively easy to conduct because a handful of wholesalers account for most sales. A law could be enacted to require wholesalers to submit periodic reports to HCFA detailing the prices at which sales took place, the volume sold at each price, and whatever other information is appropriate. That information could then be compiled by a HCFA contractor and serve as the basis for the Medicare payment.

A survey to determine market prices raises a number of issues that need to be resolved fairly, including the following:

(i) *Entities to be surveyed* -- Oncologists generally purchase their drugs from one or two wholesalers. Since wholesalers are the common source of drugs purchased by oncologists, they should be the principal entities questioned in any survey-based system.

The other two types of entities that might theoretically be considered for inclusion are group purchasing organizations (GPOs) and pharmaceutical manufacturers. ASCO opposes inclusion of prices from these sources in any survey, however, because they do not reflect typical oncologists' procurement practices.

The Justice Department data on catalog prices that HCFA almost used in lieu of AWPs included prices from GPO price lists. ASCO believes that GPO prices should not be

included in any survey-based methodology because the prices are not available to the general physician community.

Direct manufacturer prices should also generally not be included. Oncologists should not be required to obtain quotes from numerous sources to obtain a price that Medicare is willing to reimburse. Any survey process should attempt to determine the prices paid by oncologists using their customary procurement methods and thus be consistent with oncologists' continuing to purchase from only one or two wholesalers, as is now generally the practice. Including direct manufacturer prices could distort the result in some cases and provide inadequate payment to physicians who purchase from wholesalers.

(ii) *Frequency* -- Payment amounts should be designed to reflect current market prices. If the method uses surveys, there should be frequent surveys, at least monthly, to insure that the prices used are current. There should also be a mechanism to make immediate adjustments where appropriate. For example, if the manufacturer of a single source drug increases its price on January 1, there should be a way to incorporate that action into Medicare payments immediately, rather than relying on survey information for December or earlier. The principle is that if Medicare uses a system based on actual market prices, the prices used should in fact be the current market prices.

(b) Use of Price Data in a Payment Methodology

The payment method should be designed to fully cover the cost of drugs to every physician and not be limited to average or median surveyed costs. Medicare typically bases payment methods on the average or median cost. It is assumed that providers can operate at the average cost, and to the extent that they exceed average costs for some items, they will have lower-than-average costs for other items. In the case of drugs purchased by physicians, however, some physicians may be systematically disadvantaged and not be able to purchase at average prices. They should not be penalized for this circumstance. Any systematic failure to cover an oncologist's out-of-pocket expenses for drugs could easily force the physician to discontinue chemotherapy treatments. Thus, any payment method should be pegged to the 95th percentile of

surveyed prices throughout the United States or similarly be constructed to cover the full costs of virtually all physicians.

Moreover, in determining the 95th percentile of surveyed prices, sales volume that takes place at each price should be considered. This issue is related to ASCO's position that oncologists should be permitted to continue buying from one or two wholesalers and not be compelled to purchase from numerous sources to stay within the Medicare reimbursement rates. If a survey finds small wholesalers with particularly low prices on certain drugs, that finding could distort the Medicare payment rate even if those low prices do not reflect the vast majority of actual market transactions. To prevent this result, prices identified in surveys should be weighted by the approximate sales volume they represent.

In addition, there should be no effort to restrict payments to physicians in an attempt to control drug prices. In one of the Clinton Administration's proposals, payments to physicians for drugs were deliberately limited to market prices that prevailed during some past period on the theory that such a limit would inhibit price increases by drug manufacturers. Physicians should not suffer from inadequate payment based on these dubious attempts at price control.

Finally, there should be an overriding provision that permits a physician to submit evidence of the cost of a particular drug in unusual circumstances so that the physician can always receive full recovery of costs. Physicians must sometimes purchase drugs at unusually high prices, such as when a drug is bought at retail from a pharmacy in an emergency. Physicians (or patients in the case of unassigned claims) should not have to incur losses in such a circumstance.

(c) Necessity for an Add-on Amount

If the basic drug payment is based on some form of the estimated cost of the drug to physicians, there should be a percentage add-on payment to cover certain costs that would not be considered included in the chemotherapy administration payments even if those payments were set at amounts that fully covered the associated costs. These additional costs are as follows:

(i) *Drug Wastage* -- There are several sources of drug waste. In the case of single-use vials, Medicare policy is that the physician may bill for the entire vial even if only part of the vial is administered to a patient. In the case of multiple-dose vials, however, there is potential waste because the amount billed for each patient is the amount used. The extent of waste depends on the particular drug and the volume of patients seen by the practice that are receiving the drug. That is, once the drug container is opened, it must be used within a specified time period, and whether that will occur depends on whether the drug is commonly used and whether other patients are ready to receive the drug within its remaining life.

In addition to waste from multiple-dose vials, there is some waste due to product expiration. Unforeseen circumstances may result in an inability to use drugs ordered for a patient, such as when the patient stops responding to the drug, does not tolerate it, refuses it, or unexpectedly dies. Particularly if the drug is one that is used relatively infrequently, it may become outdated and must be discarded. Similarly, returns of unused product that must be refrigerated will often not be accepted by suppliers.

Spillage may also lead to product waste.

(ii) *Bad Debt (Unpaid Coinsurance)* -- Although Medicare Part B does not ordinarily cover unpaid coinsurance, there should be a special policy for drugs because physicians have expended money out-of-pocket for the drugs, and the expenses can be considerable. Because of the out-of-pocket expense, unpaid coinsurance on drugs is not the same as unpaid coinsurance on office visits or, for that matter, chemotherapy administration services.

Most Medicare patients have supplemental insurance that covers some or all of their coinsurance. For those who do not, however, coinsurance for expensive cancer drugs is often a burden that the patients cannot meet, and if Medicare does not cover the bad debt, the physician will suffer a potentially large shortfall in recovering the amounts spent to purchase the drugs. Debt collection from oncology patients is especially difficult because of the severity of the illness, the disruption of family finances by the disease, and the tendency for families to believe that debts die with the patient. It is hard to collect from extremely ill patients or their bereaved families, and, compared to other specialties, oncologists are in this situation much more often. Moreover, even patients who are believed to have secondary insurance can be the source of significant bad debt when multiple courses of chemotherapy have been furnished before the secondary insurer notifies the physician of nonpayment due to policy expiration, patient ineligibility, or other reason.

If the Medicare payment is reconfigured to reflect the estimated costs incurred by the physician, a factor for unpaid coinsurance should be included so as to keep the physician financially viable.

(iii) *Opportunity Cost of Funds Tied Up in Drug Inventory* -- At any given time, a physician may have tens of thousands of dollars of drugs on hand in the office. The funds used to purchase those drugs have an opportunity cost because the physician is not able to earn investment income on them. This is a cost that should be recognized through an add-on payment.

(iv) *Drug-related Procurement and Disposal Costs* -- The add-on payment should cover procurement costs, including staff time to order, receive, and store drugs, storage equipment, and space. Staff time related to procurement of drugs is separate from staff time related to chemotherapy administration. The inventory of drugs in an oncologist's office can be very complex and require substantial management time. In addition, there are costs involved in the disposal of toxic drugs and drug residues.

(v) *State and Local Sales Taxes* -- There should be an add-on amount to cover state and local sales and gross receipts taxes in the affected states. Again, the rationale is that if the payment methodology is intended to cover the physician's costs, it must cover all costs that are incurred when the physician provides the drug. ASCO understands that about ten states have sales taxes applicable to drugs administered in physician offices or gross receipts taxes. These taxes are significant and can exceed 6 percent.

(vi) *Amount of the Add-on* -- ASCO is not aware of any reliable data on the costs to oncologists of drug wastage, bad debt, capital, and procurement. Moreover, it would probably be difficult to develop a sound estimate of these factors across all oncologists. Accordingly, ASCO recommends that if an acquisition cost system is adopted, the amount of the percentage add-on should be 10 percent plus any applicable sales or gross receipts tax. The 10 percent suggested should be adequate to cover the costs identified.

2. Revised Methodology Based on AWP

Medicare's use of AWP as a basis for reimbursement has been criticized because the currently available AWPs are sometimes much higher than actual market prices and not because there is something inherently objectionable to Medicare's basing its payment amounts on published price information. Since AWP-based reimbursement methods are widely used throughout public and private insurance programs, it may be desirable to continue using AWP in the Medicare program if the AWPs are made more accurate. Therefore, one possible revised methodology is for Medicare to continue using published AWPs but under rules in which AWPs are legally required to reflect actual market prices.

Since AWPs are based on information submitted by manufacturers to the publishers, a law could be enacted to require manufacturers to revise the prices they submit if the difference between the average actual selling price and the published AWP exceeded some specified percentage. Most of the concern expressed about inaccurate AWPs has emphasized the very large differences between AWP and actual sales prices for certain drugs, typically multiple source drugs, not the lower 10-20 percent spreads often seen for single source drugs. The law

could require that manufacturers and distributors revise their submissions to the AWP publishers so that the average selling price is never more than a specified percentage, such as 20 percent, less than AWP. If a manufacturer wanted to reduce its average selling price in a manner that violated the requirement, it would have to precede the price reduction by first revising its submission to the AWP publishers. After consideration of the wholesalers' markup, the permissible 20 percent spread between the manufacturer's average selling price and AWP would be narrowed to an amount that has not generally been viewed as objectionable. If such an approach were adopted, the manufacturers' average selling price would need to be defined in a manner that excluded sales prices that are not directly or indirectly available to oncologists (such as prices available only to hospitals).

A system of this type would have several advantages: (1) it would maintain the administrative burden on drug manufacturers and the AWP publishers, rather than shifting it to the government or physicians as some other approaches would; (2) it would allow continued use of the AWP process with which there is broad familiarity; (3) the government could confirm the accuracy of the AWPs, at least approximately, through use of the price data submitted to HCFA for Medicaid rebate purposes; and (4) allowing a spread between typical prices and the reimbursement amount avoids some of the problems, discussed above, associated with payment amounts that are based on market surveys of acquisition cost. This approach would require legislation to impose the new requirements on manufacturers and to create penalties for violations.

Under this approach, there should still be a separate payment for state sales and gross receipts taxes in the states that have them. In addition, because payment amounts for drugs under state Medicaid programs and private insurance plans assume that the AWPs are inaccurate, there would need to a transition mechanism, such as temporary publication of two sets of prices.

3. Other Methodologies

In addition to a survey of wholesaler prices, which ASCO would support, there are various other theoretical possibilities for a source of price data to replace published AWPs. These include (1) cost-pass-through reimbursement, which would be implemented by requiring a physician to state the price paid for a drug on each claim submitted to Medicare; (2) use of wholesale acquisition cost prices; (3) surveying a sample of physicians to determine the prices they paid; and (4) using price information obtained from pharmaceutical manufacturers, such as the information on the average price at which manufacturers sell their drugs to wholesalers as currently reported to HCFA for Medicaid rebate purposes. There may be other possibilities as well.

(a) Cost-pass-through Reimbursement

ASCO would object to any payment methodology under which a physician must identify the price paid for a drug as part of each claim submitted. This approach has several serious drawbacks:

(i) *Burdensome accounting* -- Any cost reimbursement method would be extraordinarily burdensome to physician offices. Since vials may be purchased at different prices, physicians would need an elaborate tracking and accounting system to identify the price paid for the specific vial of drug administered to a specific Medicare patient. This might be a formal accounting system, such as first-in, first-out, in which the office would maintain records of the purchase price of each drug vial in chronological order. The office would then prepare bills in a strict order based on the date and time of the chemotherapy so that each vial appearing on a bill could be matched to a purchase price on a first-in, first-out basis. This would be a labor-intensive effort that would be easily subject to errors by failing to maintain the strict order

matching the order of the vials purchased with the order in which patients received the chemotherapy.

Alternatively, physicians could use a system of physical identification in which each vial would be labeled with its purchase price. As each vial is received from the distributor, a staff member would attach a label identifying the cost of the vial. Later, when the vial is used, the price information would be transferred to the patient's records and ultimately to the bill and Medicare claim. The process would require significant individualization of bills and would not permit the degree of automation available when standard charges are used, as they are currently.

(ii) *Risk of False Claims* -- Both the accounting and the physical systems of reporting prices paid would be prone to errors, since variable price information would need to be recorded properly and then be correctly transferred multiple times until it was stated on the claim form. Errors would raise the specter of being false claims and potentially subject to prosecution for fraud.

A related point is the difficulty that physicians would have in creating an audit trail for their claims. If the system of physically labeling each vial to show the price paid were used, there would not be a paper trail that government auditors could review. In other words, there would be no records proving the price paid for the specific vial administered to a particular patient. Physicians would be unable to defend themselves if the government asserted improper billing.

(iii) *Extensive Regulation of Purchases and Billing* -- In a cost reimbursement regime for drugs, the government would inevitably issue an extensive set of rules to regulate physicians' purchase transactions. That would occur because the market would attempt to adapt to a cost-pass-through payment method, and the government would find it necessary to prevent

that adaptation. For example, an obvious market response to a cost-pass-through system would be for sellers of drugs to make offers such as five vials at $50 each for every 5 vials purchased at $100 each. The purpose of such a price structure would be to permit the purchasing physician to administer the $100 vials to Medicare patients subject to cost reimbursement and to use the $50 vials for privately insured patients paid under an AWP-based or other non-cost method. Medicare would presumably object to that approach. Thus, new laws or regulations, backed by criminal or civil penalties, would be issued to govern in detail the nature of the price structures that physicians may agree to in purchasing drugs, or how physicians must allocate drugs purchased at different prices between Medicare and non-Medicare patients, or both.

That example is only one possibility of how the market would adapt. Another possibility is year-end rebates based on the volume of drugs purchased, which would raise the question of whether physicians would need to refund money to the government and patients. Bundled sales arrangements, in which medical supplies would be offered at a low price in connection with purchases of drugs at a high price, can be envisioned. The market would attempt in many currently unforeseeable ways to take advantage of a cost reimbursement system, and that would in turn trigger a vast array of detailed governmental regulations, accompanied by audits and investigations to determine whether physicians are in compliance.

ASCO could not support a system that would not only be extremely burdensome but that would also intensify governmental regulation, audits, and investigations of oncology practices.

(iv) *Reduced Competition* -- Finally, cost reimbursement of drugs would likely reduce competition and lead to higher drug prices. The Medicare program has almost entirely eliminated cost reimbursement as a payment method in favor of prospective payment systems

and fee schedules because of the undesirable effects of cost reimbursement. It would benefit Medicare in the long run to retain a system in which physicians and other drug purchasers have an incentive to seek lower prices.

(b) WAC-based Payments

There have been suggestions that a revised Medicare payment system should be based on wholesale acquisition cost ("WAC"). As mentioned earlier, WAC is the price at which manufacturers sell to wholesalers. In the case of some single source drugs, the wholesaler sells the product to the oncologist at WAC plus a mark-up. In the case of other drugs, the wholesaler sells the drug at a discount to WAC pursuant to a contract between the manufacturer and the end-user, and the wholesaler charges back the difference to the manufacturer.

ASCO does not oppose a payment system based on WAC provided that, in the case of drugs that are not subject to discounting through charge-back arrangements, the Medicare payment equals WAC plus the wholesaler's markup plus the 10 percent add-on for related costs discussed above. In the case of drugs for which discounts are offered through charge-back arrangements, a WAC-based payment system could use a different formula for computing the payment amount so long as the payment covered the actual costs incurred by all or the vast majority of oncologists. Since WAC is not a publicly available price, legislation would presumably be required to compel disclosure of that price to the Medicare program.

(c) Other Possibilities

ASCO would object to a methodology based on surveys of physicians to determine the prices they paid for drugs. This too would be unduly burdensome, especially considering the frequency with which the surveys would need to be conducted to keep Medicare payment amounts current with market prices. Moreover, it would make no sense to survey

several hundred thousand physicians, or a scientifically selected sample of that group, when there are only a few wholesalers that could be surveyed instead.

ASCO does not object to methodologies based on price information obtained from manufacturers, rather than wholesalers, **if the price information can be accurately converted to prices available from wholesalers to physicians**. If the only data available from manufacturers are average sales prices, or the average manufacturer prices calculated for Medicaid rebate purposes, there is considerable uncertainty whether such information could be successfully used in the Medicare program. Summary price information of that nature may include prices paid by hospitals and HMOs, which may be lower than prices paid by wholesalers, and an average price gives no indication of the range of prices that may be offered. Manufacturer price information should be used only if its practical utility is confirmed through careful study.

4. Effect on Hospital Outpatient Department Payments

The hospital outpatient department fee schedule includes a transitional pass-through payment methodology under which Medicare pays hospitals for cancer drugs and some other drugs based on the payment amount for office-administered drugs (95 percent of AWP). Hospital outpatient departments are an essential part of the delivery system for cancer therapy, and they must remain viable to insure that Medicare patients have access to appropriate care. Because of the linkage between the pass-through payments to hospitals and the AWP-based system, any necessary revisions in the law should be made so that changes in the payments for drugs administered in physician offices will not affect adversely the ability of hospital outpatient departments to continue providing care.

VI. CONCLUSION

ASCO supports revision of the Medicare payment system to more closely align Medicare payment amounts to the costs of drugs, drug administration, and related services. It is essential, however, that the Medicare payment amounts in a restructured system actually cover the costs involved for all or at least the vast majority of oncologists. ASCO's position can be summarized as follows:

Payments for drug administration -- The Medicare payments for chemotherapy and other drug administration are currently only a small fraction of their actual costs. The payments should be revised to cover the full costs incurred by physicians in providing such services.

Cognitive services -- Medicare should establish a new payment mechanism for chemotherapy support services to recognize payments for important services that are furnished in connection with chemotherapy but that are not now reimbursed.

Payments for drugs -- Medicare payment for drugs should be based on either (1) government surveys of wholesaler selling prices, or (2) the existing average wholesale price system as modified to limit the permissible difference between actual selling price and published average wholesale price.

- Payments should be set at amounts that will cover the costs incurred by the vast majority of oncologists and should not require oncologists to alter their typical current procurement method of buying drugs from one or two wholesalers.
- Any payment system based on an estimate of market prices should include a 10 percent add-on to cover additional drug-related costs, such as inventory expenses, bad debt, and wastage.
- Medicare should also pay state and local sales taxes and gross receipts taxes.

Some other payment methods, such as those based on wholesale acquisition cost or data supplied by manufacturers, could be used if they meet these criteria. A system of reimbursing each physician for the specific costs incurred by the physician for drugs administered to Medicare patients has serious defects, however, and should not be adopted.

It must be kept in mind that the resolution of these issues will determine the nature of the cancer treatment delivery system. If Medicare payments are not adequate to support the current largely office-based delivery system for cancer chemotherapy, a much larger hospital-based system would have to be restored. Since hospitals currently lack capacity, the transition would be difficult and extremely disruptive to the treatment of countless seriously ill seniors. Accordingly, ASCO urges that patient access to the current treatment delivery system be preserved by Medicare's adopting ASCO's recommendations for payment reform.

APPENDIX A

ESTIMATES OF CLINICAL STAFF TIME

96410 (First hour of chemotherapy infusion)

Pre-Procedure:

Obtain medical history — 9 minutes
- Review of systems
- Toxicities
- Complication
- Medication list review
  - Prescribed current medications
  - Over-the-counter medications
- Lab values review
  - Complete blood count
  - Chemistry
- Psycho-social review

Pre-procedure education — 10 minutes
- Review:
  - Medication side effects
  - Disease process
  - IV instructions
    - IV flow signs/symptoms
    - Vesicant instructions
      - Infiltration
  - Care planning process
    - Review the treatment plan established by physician and patient (HCFA)

Greet patient/provide gowning — 2 minutes
- Verify patient identification
- Verify orders
- Verify drug vs. diagnosis
- Verify infusion time
- Verify insurance coverage completed
- Verify consent obtained
- Time allotment for gowning

Perform room preparation — 10 minutes
- Gather supplies
  - IV pole
  - Pump
    - Equipment maintenance

Program pump
Alarm testing
Electrical safety
IV start equipment
Catheter flush supplies
Solution
Syringes
Alcohol wipes
Personal protective equipment
Gloves
Gown
Mask
Goggles
Hazardous waste container

Prep patient/drug mixing 22 minutes

Medication interactions
Verify orders per protocol
Calculate dose
Maximum dose per drug
Cumulative dose per patient
Assemble supplies
Solutions
Drugs
Tubings
Syringes
Assess patient and drug for proper solution
Appropriate amount
Glass vs. plastic
Assess drug stability
Prepare labels
Document lot #s
Document expiration dates
Hood preparation and maintenance
Cleaning prior to mixing
Certified Bio Safety Cabinet (BSC)
Prepare drugs and flushes (may be more than 2 drugs)
Double check
1 over 1 validation of drug and vial selected
Prime tubing
Inventory management
Reorder of drugs
Re-stocking of drugs
Maintenance of Material Safety Data Sheets (MSDS)

Obtain vital signs 2 minutes

Blood pressure
Temperature
Pulse
Height
Weight
Calculate Body Surface Area (BSA)
Verify with orders and dose recommendations

Total for Pre-procedure **55 minutes**

Intra-procedure:

Administer chemotherapy 27 minutes
Access IV
Peripheral vs. central line
Vein selection
Single IV vs. double
Establish patency
Blood return
Begin infusion
Regulate rate
Monitor solutions
Multi bag infusion in first hour
Assessments every 15 minutes
Patient response/tolerance
Interventions as needed
IV site assessment
Vital signs
Flush IV catheter
Discontinue IV
Remove device
Cover and maintain pressure
Site assessment
Documentation of start-stop times

Post-procedure:

Monitor Patient 5 minutes
Safe practice assessment
Adverse reactions
Site reassessment
Bleeding

Clean treatment area/equipment — 2 minutes

- OSHA compliance
  - Dispose of hazardous waste
  - Change linen
  - Remove equipment
  - Wipe down area

Post-procedure education — 10 minutes

- Drug related toxicities (longer first visit)
- Symptom management
  - Fever/chills/reactions/nausea
- Prescriptions
- Family education
- Verify follow-up appointments
- Home health arrangement
- IV catheter care (central line)
  - Flushing
  - Dressings

Complete documentation on medical forms — 5 minutes

- Lab flow sheet
  - Complete blood count
  - Chemistry
  - Evaluate and trend
- Infusion flow sheet
  - Drug/dose
  - Solution/volumes
  - Length of time
  - Cumulative dose
- Vital signs
  - Blood pressure/temperature/pulse
  - Height
  - Weight
  - Body Surface Area
- Instructions given
  - Delayed hypersensitivity
  - Level of understanding
- Response
  - Tolerance to regimen
- Prescriptions
  - Nausea
  - Pain
  - Refills

Follow-up phone calls — 15 minutes

Outpatients vs. inpatients
- Home care
  - Order verification
  - Patient changes
  - Medication changes
- Family
- Insurance
- Labs to other MDs
- Labs to patients
- Scheduling
- Prescriptions new and refills
- Symptom management
- Obtain orders
- Call to pharmacy
- Documentation notes of phone calls and MD instructions
- Follow-up calls
  - Day after first treatment
    - Review side effects
    - Tolerance
    - IV site
    - Questions

Regulatory compliance — 2 minutes

Total for Post-procedure — **39 minutes**

96408 (Chemotherapy administration by push)

Same times as for 96410, except intra-procedure time is 15 minutes instead of 27 minutes.

CPEP SUMMARY OF CLINICAL STAFF ESTIMATE
(From the HCFA Internet site)

CPT CODE	STAFF TYPE	RATE	DESCRIPTION	MINUTES
96408	10137	0.497	RN/OCN	102
96410	10137	0.497	RN/OCN	121

SUPPLIES USED IN 96408 AND 96410
(From the HCFA Internet site)

CPT CODE	HCFA SUPPLY CODE	DESCRIPTION	UNIT	COUNT	PRICE	CONVERSION	COST
96408	11106	drape, sheet	item	1	0.26	1	0.26
96408	11107	patient gown, disposable	item	1	0.57	1	0.57
96408	11111	exam table paper	foot	1	0.015	7	0.105
96408	11302	gloves, non-sterile	pair	1	0.12	2	0.24
96408	11303	gloves, disp., nitrile or chemo chemical	pair	1	0.52	1	0.52
96408	11304	gown, staff, impervious, disposable	item	1	1.38	1	1.38
96408	11509	thermometer probe cover, disposable	item	1	0.069	1	0.069
96408	31101	swab, alcohol	item	1	0.017	2	0.034
96408	31502	band aid, 3/4" x 3"	item	1	0.047	1	0.047
96408	91105	needle, butterfly 20 to 24 gauge	item	1	0.52	1	0.52
96408	91110	iv infusion set	set	1	1.25	1	1.25
96408	91402	needle, 18 to 24 gauge	item	1	0.12	3	0.36
96408	91407	syringe, 10 cc or 12 cc	item	1	0.23	1	0.23
96408	91408	syringe, 1ml	item	1	0.25	1	0.25
96408	91409	syringe, 20 cc	item	1	0.62	1	0.62
96408	91412	syringe. 50 cc and 60 cc	item	1	1.03	1	1.03
96408	91414	water, sterile	ml	30	1.2	60	2.4
96410	11106	drape, sheet	item	1	0.26	1	0.26
96410	11107	patient gown, disposable	item	1	0.57	1	0.57
96410	11111	exam table paper	foot	1	0.015	7	0.105
96410	11302	gloves, non-sterile	pair	1	0.12	2	0.24
96410	11303	gloves, disp., nitrile or chemo chemical	pair	1	0.52	1	0.52
96410	11304	gown, staff, impervious, disposable	item	1	1.38	1	1.38
96410	11509	thermometer probe cover, disposable	item	1	0.069	1	0.069
96410	31101	swab, alcohol	item	1	0.017	2	0.034
96410	31502	band aid, 3/4" x 3"	item	1	0 047	1	0.047
96410	91105	needle, butterfly 20 to 25 gauge	item	1	0.52	1	0.52

96410	91107	infusion pump cassette	item	1	16.79	1	16.79
96410	91110	iv infusion set	set	1	1.25	1	1.25
96410	91402	needle, 18 to 24 gauge	item	1	0.12	3	0.36
96410	91407	syringe, 10 cc or 12 cc	item	1	0.23	1	0.23
96410	91408	syringe, 1ml	item	1	0 25	1	0.25
96410	91409	syringe, 20 cc	item	1	0.62	1	0.62
96410	91412	syringe, 50 cc and 60 cc	item	1	1.03	1	1.03
96410	91414	water, sterile	ml	30	1.2	60	2.4

EQUIPMENT USED IN 98408 AND 96410
(From the HCFA Internet site)

CPT CODE	TIME	PXEQ	EQUIP CODE	DESCRIP.	LIFE	PRICE	INT RATE	CAP FRAC	ANN FACT	COST MIN
96408	92	0.12	E91003	ventilator hood and blower	10	602.55	0.11	0.1698	0.2198	0.0013
96408	92	0.17	E91004	Chemo couch	10	895	0.11	0.1698	0.2198	0.0019
96410	111	0.14	E91003	ventilator hood and blower	10	602.55	0.11	0.1698	0.2198	0.0013
96410	111	0.21	E91004	Chemo couch	10	895	0.11	0.1698	0.2198	0.0019
96410	111	0.97	E91001	infusion pump	10	4150	0.11	0.1698	0.2198	0.0087

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

JAMES STRACKA, Plaintiff, v. INTERNATIONAL BUSINESS MACHINES CORPORATION, Defendant, v. JAMES STRACKA and LEIF SVALGAARD, Counterclaim-Defendants.	§ § § § § § § § § § § § § §	CIVIL ACTION NO. H-04-2450 (KMH)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT INTERNATIONAL BUSINESS MACHINE'S MOTION TO STRIKE THE EXPERT REPORT OF DAVID NIMMER

Pursuant to Fed. R. Evid. 702 and 704, defendant International Business Machines Corporation ("IBM") hereby moves this Court for an order striking the expert report of David Nimmer (the "Nimmer Report" or "Report") for the reasons set forth below.

INTRODUCTION

The Nimmer Report impermissibly exceeds the boundaries set by Fed. R. Evid. 702 and 704 for an admissible expert witness opinion because it does not assist the trier of fact in resolving an issue of fact. Rather, the Nimmer Report improperly presents legal analysis and conclusions of law. The use of expert witness testimony to present such analysis and conclusions is prohibited in this Circuit. Accordingly, IBM's motion to strike should be granted.

ARGUMENT

Fed. R. Evid. 702 and 704 set forth certain limitations on the admissibility of expert testimony. In particular, expert testimony is admissible only with respect to issues of fact. Thus, Rule 702 states that expert testimony is admissible

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In addition, Rule 704 (a) states in pertinent part that "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." In other words, under both Fed. R. Evid. 702 and 704, expert testimony is admissible only if it concerns an issue of fact, rather than an issue of law. However, the substance of the Nimmer Report consists of nothing but legal analysis and conclusions of law. Accordingly, IBM's motion to strike should be granted.

In essence, the Nimmer Report is nothing more than a legal brief. Having summarized the documents reviewed in preparing the Report, Mr. Nimmer sets forth two "Questions Presented":

(a) Whether the actions taken by Leif Svalgaard in developing the Fast400 product amount to copyright infringement under 17 U.S.C. § 501;

(b) Whether the development and sale of the Fast400 product constitutes a violation of the anti-circumvention provisions of the Digital Millenium Copyright Act (DCMA), 17 U.S.C. §1201(a)(2) and (b)(1). Report, ¶ 4.

It is apparent that these "Questions Presented" will be answered with legal conclusions. Having set forth these "Questions Presented," as well as certain facts as Mr. Nimmer understands them

(Report ¶¶ 5-19), the Nimmer Report "frames the inquiry" regarding copyright infringement and the DMCA by reviewing the relevant statutes, and examining the elements that IBM must establish to prove a violation of each. Report, ¶¶ 25-34 (copyright infringement) and 42 (DCMA). The Nimmer Report then applies this law to the facts (again, as Mr. Nimmer understands them) and draws two legal conclusions, namely, (1) that Leif Svalgaard has not infringed IBM's copyrights and (2) that Svalgaard has not violated the DMCA. Report, ¶¶ 35-41 (copyright infringement) and 43-53 (DMCA).

Our legal system divides fact-finding from legal analysis for good reasons. "Each courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards." U.S. v. Pal-Tech, Inc., 231 F.Supp.2d 94, 98-99 (D.C. 2002) (granting motion to strike expert witness report). If each party to a litigation were allowed to present an "expert" who offered legal analysis tailored to its own position, it would be difficult, if not impossible, for a jury to reach well-founded conclusions. Askanase v. Fatjo, 130 F.3d at 673; see also Specht v. Jensen, 853 F.2d 805, 808 (10th Cir. 1988). Indeed, each side's expert would be offering no more than the lawyers of each party. In re Air Crash Disaster at New Orleans, LA, v. Pan American World Airways, 795 F.2d 1230, 1233 (5th Cir. 1986). That is why Rule 703 limits expert witness' testimony to issues of fact.

Rule 704 permits an expert witness to give an opinion on ultimate facts, but not on ultimate issues of law. Smogor v. Enke, 874 F.2d 295, 296 (5th Cir. 1989); Owen, 698 F.2d at 240. Were this not the case, it would be too easy for a jury to conclude that the legal issue is "whatever an expert witness says it is, and trial courts must be wary lest the expert become nothing more than an advocate of policy before the jury." In re Air Crash Disaster at New Orleans, LA, 795 F.2d at 1233.

The Nimmer Report is thus a perfect example of the kind of expert testimony that is inadmissible in this Circuit. Askanase v. Fatjo, 130 F.3d 657, 673 (5th Cir. 1997); In re Air Crash Disaster at New Orleans, LA, v. Pan American World Airways, 795 F.2d 1230, 1233 (5th Cir. 1986); Owen v. Kerr-McGee Corp., 698 F.2d 236, 240 (5th Cir. 1983) ("[A]llowing an expert to give his opinion on the legal conclusions to be drawn from the evidence both invades the court's province and is irrelevant.").[1]

CONCLUSION

The Nimmer Report improperly presents legal analysis and conclusions. Under Fed. R. Evid. 703 and 704 and the law of this Circuit, expert witness' testimony is limited to issues of fact. Accordingly, IBM's motion to strike should be granted.

Respectfully submitted,

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[1] It should be noted that other Circuits agree. See, *e.g.*, Christiansen v. City of Tulsa, 332 F.3d 1270, 1283 (10th Cir. 2003) ("Generally, an expert may not state his or her opinion as to legal standards nor may he or she state legal conclusions drawn by applying the law to the facts."); U.S. v. Duncan, 42 F.3d 97, 103 (2d Cir. 1994) ("Although an expert may opine on an issue of fact within the jury's province, he may not give testimony stating ultimate legal conclusions based on those facts.").